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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION

UNITED STATES OF AMERICA,

and

THE STATE OF NORTH CAROLINA,

ex rel. LISA WHEELER

Plaintiffs,

vs.

ACADIA HEALTHCARE COMPANY, INC.; CRC HEALTH, LLC; ATS OF NORTH CAROLINA, LLC d/b/a MOUNTAIN HEALTH SOLUTIONS ASHEVILLE, d/b/a ASHEVILLE COMPREHENSIVE TREATMENT CENTER, d/b/a MOUNTAIN HEALTH SOLUTIONS NORTH WILKESBORO (MHS), d/b/a NORTH WILKESBORO COMPREHENSIVE TREATMENT CENTER.

Defendants.

FILED
ASHEVILLE, N.C.
SEP 10 2021
U.S. DISTRICT COURT
W. DIST. OF N.C.

Case No. 1:21cv241

COMPLAINT **FILED IN CAMERA SEALED**, PURSUANT TO 31 U.S.C. § 3730(b)(2)

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DEMAND FOR JURY TRIAL

NOW COMES PLAINTIFF-RELATOR, Lisa Wheeler, by and through her attorneys, on behalf of the United States of America ("United States") and the State of North Carolina to recover losses from false claims submitted to the Medicaid and Medicare programs as a result of the sustained fraudulent conduct of Defendants Acadia Healthcare Company, Inc. ("Acadia"), CRC Health, LLC ("CRC"), and ATS of North Carolina, LLC, d/b/a Mountain Health Solutions Asheville, d/b/a Asheville Comprehensive Treatment Center, d/b/a Mountain Health Solutions North Wilkesboro (MHS), d/b/a North Wilkesboro Comprehensive Treatment Center ("ATS"). This action is brought under the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"), seeking

treble damages and civil penalties, as well as the North Carolina False Claims Act, N.C. Gen. Stat. § 1-607, *et seq.*, and other laws as set forth herein.

I. INTRODUCTION

1. The United States is in the throes of an opioid epidemic that has devastated the lives of many families and has cost billions of dollars to abate.

2. While the opioid epidemic long predated the COVID-19 pandemic, the joblessness, depression, and sense of isolation created by the viral pandemic have exacerbated the opioid epidemic.

3. The efforts of healthcare professionals to identify and treat individuals with Opioid Use Disorder have seen some success, but there is much work to be done.

4. Defendants own and operate facilities that treat Opioid Use Disorder and, upon information and belief, have received hundreds of millions of dollars—if not more—from federal and state healthcare programs for this treatment.

5. One of the primary services offered by Defendants is Medication-Assisted Treatment ("MAT") for individuals diagnosed with an Opioid Use Disorder.

6. Defendants treat opioid addiction in a variety of settings, including inpatient, intensive outpatient, Opioid Treatment Programs ("OTPs"), and Office Based Opioid Treatment ("OBOT").

7. Provision of these services is heavily regulated by federal and state law.

8. Many individuals, including Medicare and Medicaid beneficiaries, have sought treatment from Defendants, including OTP and OBOT services.

9. Federal law, State law, and the governmental and nongovernmental entities that certify and accredit clinics, like those owned and operated by Defendants, require that patients in OTPs and OBOTs be put on a treatment plan that includes group and/or individual therapy.

10. The requirement of group and/or individual therapy is in place to help treat underlying trauma, discover the cause of patients' addiction, and prevent relapse.

11. Upon information and belief, Defendants are not, in fact, providing minimally adequate therapy and counseling to patients.

12. For example, Defendants' clinics in Asheville, North Carolina and North Wilkesboro, North Carolina are falsifying their group therapy records.

13. To accomplish this, the clinics have patients fill out pre-printed worksheets on topics like loneliness and forgiveness.

14. Upon information and belief, the patients never discuss their responses with a therapist or counselor in an individual or group session.

15. Instead, the clinics prepare fraudulent group therapy notes, which state that the patients participated in group therapy sessions and discussed their responses to the worksheets with therapists and/or counselors.

16. The falsified therapy notes are detailed, widespread, and violate both the law and the evidence-based standards underlying Opioid Use Disorder treatment.

17. Upon information and belief, these records are falsified in order to save time and money.

18. Upon information and belief, these records are falsified in order to give the illusion that Defendants are:

(a) Providing appropriate treatment to individuals with Opioid Use Disorder;

(b) Complying with the terms of patients' treatment plans;

(c) Complying with State and Federal law;

(d) Complying with their certification and accreditations;

(e) Complying with their provider agreements; and

(f) Complying with the Corporate Integrity Agreement, which is discussed below.

19. Moreover, Defendants' false and fraudulent conduct is not novel. In 2019, Defendant Acadia and Defendant CRC entered into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General of the United States Department of Health and Human Services ("HHS-OIG").

20. This CIA was a result of a $17 million settlement in West Virginia for Medicaid fraud related to false and fraudulent billing for drug testing.

21. Defendant ATS is a "Covered Person" under the CIA; therefore, it applies to the conduct of all Defendants.

22. The Corporate Integrity Agreement imposes heightened training and disclosure requirements and requires that Defendants report *any* fraudulent or illegal conduct to the United States.

23. Upon information and belief, Defendants have actively concealed their fraudulent conduct from the United States and the State of North Carolina in order to preserve their status as Medicare and Medicaid providers.

24. In so doing, Defendants have submitted, and, upon information and belief, continue to submit, claims to Medicare and Medicaid for Opioid Use Disorder treatment.

25. When submitting those claims, Defendants expressly and/or impliedly certified to federal and state healthcare programs that they were:

(a) Providing appropriate treatment to individuals with Opioid Use Disorder;

(b) Complying with the terms of patients' treatment plans;

(c) Complying with State and Federal law;

(d) Complying with their certification and accreditations;

(e) Complying with their provider agreements; and

(f) Complying with the CIA.

26. As a result of these materially false statements, certifications, and claims, and without knowledge of their falsity, the governmental Plaintiffs have paid, and, upon information and belief, continue to pay, Defendants' false and fraudulent claims.

II. JURISDICTION AND VENUE

27. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

28. This action arises under the False Claims Act, 31 U.S.C. §§ 3728 *et seq.*

29. This Court has jurisdiction over this case pursuant to 31 U.S.C. §§ 3730(b) and 3732(a).

30. This Court also has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1345.

31. Additionally, the Court has jurisdiction over the state-law counts asserted in this Complaint under both 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367, because the state-law claims arise from the same transaction or occurrence as the federal claims and because these claims are so related to the federal claims that they form part of the same case or controversy under Article III of the United States Constitution.

32. At all times material to this Complaint, Defendants regularly conducted substantial business within the State of North Carolina, maintained permanent employees and offices in North Carolina, and made and are making significant sales within North Carolina.

33. Defendants are thus subject to personal jurisdiction in North Carolina.

34. Venue lies in this district pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) because Defendants resides in and/or has transacted business within this Court's jurisdiction, and the acts set out herein occurred in the Western District of North Carolina.

III. PARTIES

35. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

A. Governmental Plaintiffs

36. The United States of America is recovering on behalf of its agencies, including the United States Department of Health and Human Services ("DHHS") and the Centers for Medicare & Medicaid Services ("CMS").

37. The State of North Carolina is recovering on behalf of its agencies, including the North Carolina Department of Health and Human Services.

B. Relator Wheeler

38. Relator Lisa Wheeler is a resident of Candler, North Carolina.

39. Relator Wheeler is a practicing Physician Assistant who treats patients in the areas of addiction medicine.

40. Relator Wheeler is employed as an independent contractor by Defendant ATS of North Carolina, LLC d/b/a Asheville Comprehensive Treatment Center, LLC pursuant to a Professional Services Agreement.

41. Relator has served as an independent contractor for Defendant ATS since January 2014.

42. Relator currently serves as the Assistant Medical Director for the Asheville Comprehensive Treatment Center.

43. Relator is an original source of this information and has voluntarily provided this information to the United States and the State of North Carolina prior to filing this Complaint.

C. Defendant Acadia Healthcare Company, Inc.

44. Defendant Acadia is a for-profit corporation organized under the laws of the State of Delaware with its principal place of business in Franklin, Tennessee.

45. At all times relevant herein, Defendant Acadia—operating independently and through its subsidiaries Defendant CRC and Defendant ATS—was doing business throughout the United States, including in the Western District of North Carolina.

46. Defendant Acadia is one of the largest providers of behavioral healthcare services and addiction treatment in the United States.

47. According to Defendant Acadia's marketing materials, it is the "largest stand-alone behavioral health company in the U.S."[1]

48. As of June 30, 2021, Defendant Acadia operated a network of 229 behavioral healthcare facilities with approximately 10,100 beds in 40 states and Puerto Rico.

49. Defendant Acadia employees more than 20,000 employees and serves approximately 70,000 patients daily in a variety of settings, including inpatient psychiatric hospitals, specialty treatment facilities, residential treatment centers, and outpatient clinics.

[1] *About Acadia Healthcare*, Acadia Healthcare, https://www.acadiahealthcare.com/about/.

50. As of December 31, 2020, Defendant Acadia owned and operated facilities in the following states: Alaska, Arizona, Arkansas, California, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

51. Upon information and belief, Defendant Acadia owns and/or operates substance abuse treatment facilities—by way of subsidiary entities—in each of these states.

52. Additionally, Defendant Acadia owns and operates facilities in Puerto Rico and the United Kingdom.

53. Defendant Acadia classifies 38% of its facilities as "specialty treatment facilities," which includes "Comprehensive Treatment Centers" ("CTCs").

54. Defendant Acadia's CTCs specialize in providing substance abuse treatment, including using MAT for individuals addicted to opioids.

55. According to its February 26, 2021, Form 10-K filed with the United States Securities and Exchange Commission, each of Defendant Acadia's "CTCs provide a range of comprehensive substance abuse treatment support services that include medical, counseling, vocational, educational, and other treatment services."[2]

56. Defendant Acadia further stated in its February 26, 2021, Form 10-K that its "behavioral therapies are delivered in an array of treatment models that may include individual

[2] Form 10-K, Acadia Healthcare Company, Inc, United States Securities and Exchange Commission, at 7, *available at* https://acadiahealthcare.gcs-web.com/static-files/8498a603-f30a-4208-ac68-f8cbfb14151b [hereinafter "10-K"].

and group therapy, intensive outpatient, outpatient, partial hospitalization/day treatment, road to recovery and other programs that can be either abstinent or medication assisted based."[3]

57. Defendant Acadia regularly submits, or causes to be submitted, claims for Opioid Use Disorder treatment—including, but not limited to, MAT, OTP, and OBOT services—to Medicare and Medicaid.

58. In 2020, Defendant Acadia received 49% of its revenue from Medicaid and 16% of its revenue from Medicare.

59. Moreover, upon information and belief, Defendant Acadia receives Medicaid payments from 46 states, the District of Columbia, and Puerto Rico.

60. Defendant Acadia has been a publicly traded company on NASDAQ since 2011 and generates approximately $2.1 billion in annual revenue.

61. Upon information and belief, approximately $1.365 billion of that yearly revenue (65%) comes from Medicare and Medicaid payors.

62. Because of the COVID-19 pandemic and the stressors that have caused more Americans to develop new mental health and substance use disorders, Defendant Acadia expects its revenue to continue to increase for years to come.

D. CRC Health, LLC

63. Defendant CRC is a limited liability company organized under the laws of the State of Delaware with its principal place of business in Franklin, Tennessee.

64. Upon information and belief, Defendant CRC shares its principal place of business with Defendant Acadia and Defendant ATS in Franklin, Tennessee.

[3] *Id.*

65. At all times relevant herein, Defendant CRC—operating independently and through its parent corporation, Defendant Acadia, and its subsidiary, Defendant ATS—was doing business throughout the United States, including in the Western District of North Carolina.

66. As of 2014, Defendant CRC claimed to be the largest provider of specialized behavioral healthcare services in the United States, with over 140 treatment programs and 44,000 patients per day.

67. One of Defendant CRC's primary focuses was, and still is, providing addiction treatment services and mental health services.

68. On October 29, 2014, Defendant CRC announced that it entered into an agreement to be acquired by Defendant Acadia. In this announcement, Defendant Acadia's Chairman and Chief Executive Officer, Joey Jacobs, stated:

> We expect our combination with CRC to be a great transaction for both Acadia and CRC. We believe the addiction treatment markets that CRC serves represent a very meaningful and accretive growth opportunity. As a well-established market leader, CRC will provide Acadia with an outstanding platform for growth in this fragmented market. We further expect to support CRC in taking advantage of additional growth opportunities through both our access to capital and the expertise evident in the successful long-term growth record of Acadia's management team.[4]

69. Upon information and belief, Defendant CRC is now a wholly-owned subsidiary of Defendant Acadia.[5]

70. Upon information and belief, Defendant CRC provides substance abuse treatment services for its parent corporation, Defendant Acadia, and through subsidiary companies, such as Defendant ATS.

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[4] *CRC Health Group to be Acquired by Acadia Healthcare*, PR Newswire, https://www.prnewswire.com/news-releases/crc-health-group-to-be-acquired-by-acadia-healthcare-280852262.html.

[5] *See* 10-K, supra note 2, at 181 (listing "CRC Health, LLC" as a subsidiary of Defendant Acadia).

71. Upon information and belief, Defendant CRC provides services in the following states: Alaska, Arizona, Arkansas, California, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

72. Additionally, upon information and belief, Defendant CRC also provides substance abuse treatment services in Puerto Rico and the United Kingdom.

73. Defendant CRC operates OTPs across the United States, including in the State of North Carolina.

74. Defendant CRC provides OBOT across the United States, including in the State of North Carolina.

75. Upon information and belief, Defendant CRC provides a variety of other Opioid Use Disorder services, both with and without MAT, across the United States, including in the State of North Carolina.

76. Upon information and belief, Defendant CRC regularly submits, or causes to be submitted, claims for Opioid Use Disorder treatment—including, but not limited to, MAT, OTP, and OBOT services—to Medicare and Medicaid.

77. As discussed below, many of Defendant CRC's facilities in North Carolina operate under the corporate umbrella of Defendant ATS.

78. However, upon information and belief, Defendant CRC operates similar facilities in other states by way of a variety of other subsidiary corporate entities.

79. Upon information and belief, Defendant CRC is operating under the guidance, supervision, direction, and/or control of Defendant Acadia.

E. Defendant ATS of North Carolina, LLC

80. Defendant ATS is a limited liability company organized under the laws of the State of North Carolina with its principal place of business in Franklin, Tennessee.

81. Upon information and belief, Defendant ATS shares its principal place of business with Defendant CRC and Defendant Acadia in Franklin, Tennessee.

82. At all times relevant herein, Defendant ATS—operating independently and through its parent companies, Defendant Acadia and Defendant CRC—was doing business throughout the United States, including in the Western District of North Carolina.

83. Upon information and belief, Defendant ATS is a subsidiary of Defendant Acadia and Defendant CRC.[6]

84. Defendant ATS operates substance abuse treatment facilities in cities across the State of North Carolina, including, but not limited to, Asheville and North Wilkesboro.

85. According to Defendant Acadia's February 26, 2021, Form 10-K, Defendant ATS operates substance abuse treatment facilities in the following locations in North Carolina: Fayetteville, Pinehurst, Goldsboro, North Wilkesboro, Asheville, and Winston-Salem.[7]

86. Defendant ATS's Asheville facility ("the Asheville facility") is marketed as the "Asheville Comprehensive Treatment Center."

87. However, the Asheville facility also does business as "Mountain Health Solutions Asheville."

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[6] *See id.* at 180 (listing "ATS of North Carolina, LLC" as a subsidiary of Defendant Acadia).

[7] *See* 10-K, supra note 2, at 180 (listing the various "ATS of North Carolina LLC" locations).

88. Defendant ATS's North Wilkesboro facility ("the North Wilkesboro facility") is marketed as the "North Wilkesboro Comprehensive Treatment Center."

89. However, the North Wilkesboro facility also does business as "Mountain Health Solutions North Wilkesboro (MHS)."

90. Relator has direct knowledge of the operations at Defendant ATS's operations at the Asheville facility and North Wilkesboro facility.

91. Upon information and belief, Defendant ATS operates other OTPs and OBOT programs across the State of North Carolina.

92. Upon information and belief, these facilities operate in a similar manner to the Asheville and North Wilkesboro facilities, as they are operated by the same parent companies—Defendant Acadia and Defendant CRC.

93. Upon information and belief, ATS's Managing Member is Defendant CRC.

94. Defendant ATS is the primary entity involved in face-to-face patient encounters with Defendants' patients in North Carolina.

95. Upon information and belief, Defendant ATS regularly submits, or causes to be submitted, claims for Opioid Use Disorder treatment—including, but not limited to, MAT, OTP, and OBOT services—to Medicare and Medicaid.

96. Upon information and belief, Defendant ATS is operating under the guidance, supervision, direction, and/or control of Defendant CRC and Defendant Acadia.

IV. FEDERAL AND STATE FALSE CLAIMS ACTS

97. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

A. The Federal False Claims Act

98. The FCA provides for the award of treble damages and civil penalties for, *inter alia*, knowingly causing the submission of false or fraudulent claims for payment to the United States government. 31 U.S.C. § 3729(a)(1).

99. The FCA provides, in pertinent part, that a person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (a)(1)(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
>
> . . .
>
> (a)(1)(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990[8] (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729.

[8] By virtue of 28 C.F.R. § 85.3(a)(9), the penalty range for violations occurring on or before November 2, 2015, has increased to a minimum of $5,500 and a maximum of $11,000 per violation. The penalties have continually been adjusted for inflation, and the minimum penalty is currently $11,665 and the maximum penalty is $23,331 per violation. *See* 85 Fed. Reg. 37004.

For purposes of the False Claims Act,

> the term "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information; and require no proof of specific intent to defraud.

32 U.S.C. § 3729(b)(1). Moreover, the term "material" "means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

B. North Carolina False Claims Act

100. N.C. Gen. Stat. § 1-607(a) provides:

> Any person who commits any of the following acts shall be liable to the State for three times the amount of damages that the State sustains because of the act of that person. A person who commits any of the following acts also shall be liable to the State for the costs of a civil action brought to recover any of those penalties or damages and shall be liable to the State for a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000), as may be adjusted by Section 5 of the Federal Civil Penalties Inflation Adjustment Act of 1990, P.L. 101-410, as amended, for each violation:
>
> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
>
> (3) Conspires to commit a violation of . . . this section.
>
> . . .
>
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

101. "Knowingly" is defined as "[w]henever a person, with respect to information, does any of the following:

a. Has actual knowledge of the information.

b. Acts in deliberate ignorance of the truth or falsity of the information.

c. Acts in reckless disregard of the truth or falsity of the information. Proof of specific intent to defraud is not required."

N.C. Gen. Stat. § 1-606(4).

102. North Carolina's False Claims Act is intended "to deter persons from knowingly causing or assisting in causing the State to pay claims that are false or fraudulent and to provide remedies in the form of treble damages and civil penalties when money is obtained from the State by reason of a false or fraudulent claim." N.C. Gen. Stat. § 1-605(b).

C. North Carolina Medical Assistance Provider False Claims Act

103. N.C. Gen. Stat. § 108A-70.12 makes it unlawful for any provider of medical assistance under the Medical Assistance Program to:

(1) Knowingly present, or cause to be presented to the Medical Assistance Program a false or fraudulent claim for payment or approval; or

(2) Knowingly make, use, or cause to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Medical Assistance Program.

104. A provider of medical assistance who violates this statute is subject to civil penalties of between $5,000 and $10,000 as well as treble damages. N.C. Gen. Stat. § 108-70.12(b).

V. GOVERNMENT HEALTHCARE PROGRAMS AND OPIOID USE DISORDER

105. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

A. The Opioid Crisis in America

106. Opioids have been used for thousands of years to treat various medical conditions, including pain, diarrhea, and coughs.

107. Most commonly, however, opioids are used for pain relief.

108. Common opioids include codeine, oxycodone, hydrocodone, hydromorphone, morphine, heroin, and fentanyl.

109. For many years, opioids were commonly prescribed to individuals with acute and chronic pain.

110. Often, patients were not provided any information about the addictive properties of opioids.

111. Some opioid medications contain a combination of an opioid and over-the-counter pain medication, like acetaminophen (i.e., Vicodin and Percocet), aspirin (i.e., Percodan), or ibuprofen (i.e., Vicoprofen).

112. While these combination medications are effective for individuals with mild to moderate pain, the presence of over-the-counter medications with their own negative side effects, such as ulcers or liver damage, limits their efficacy for individuals in severe pain.

113. In response to this problem, much stronger opioid medications like Oxycontin (i.e., oxycodone) and Opana (i.e., oxymorphone) became popular.

114. Pharmaceutical companies aggressively marketed these medications, frequently promoting the pills as non-addictive if used as prescribed and claiming that proprietary extended-release formulations were unable to be abused.

115. Tragically, the pills were, in fact, addictive and the "abuse deterrent" formulations could easily be circumvented.

116. Individuals who obtained these medications from a doctor or through diversion often took excessive doses on a regular basis which, in turn, increased their tolerances.

117. The result was, in many ways, inevitable: widespread addiction.

118. In recent years, physicians' prescribing habits have changed, and opioids are prescribed less frequently and in much lower doses.

119. While this led to fewer pills in peoples' medicine cabinets and, thus, fewer pills subject to illegal diversion, many individuals were left with severe addictions.

120. Some longtime patients were rapidly tapered to lower doses. Others were simply cut off by their doctors.

121. This, in turn, led to many individuals suffering from opioid withdrawal.

122. Early withdrawal symptoms typically begin within 24 hours after a user stops using opioids, though they can begin much earlier in severely opioid dependent individuals.

123. People going through opioid withdrawal suffer from symptoms ranging from muscle aches and anxiety to diarrhea, nausea, and high blood pressure.

124. Individuals in opioid withdrawal know that there is one sure-fire cure to stop the pain and misery: more opioids.

125. But the decreased supply of prescribed opioids made that difficult, if not impossible, for many people who were tapered or cutoff by their doctors.

126. Again, the result was inevitable: increased use of non-pharmaceutical opioids such as heroin and fentanyl.

127. It is difficult to quantify the devastation that has resulted from this, but the statistics that are available are staggering:

(a) "In 2017, health care providers across the [United States] wrote more than 191 million prescriptions for opioid pain medication—a rate of 58.7 prescriptions per 100 people."[9]

(b) "Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them."[10]

(c) "Between 8 and 12 percent of people using an opioid for chronic pain develop an opioid use disorder."[11]

(d) "An estimated 4 to 6 percent who misuse prescription opioids transition to heroin."[12]

(e) Nearly 841,000 people have died from a drug overdose since 1999. More than 70% of these deaths in 2019 involved an opioid.[13]

(f) In 2019 alone, nearly 50,000 people in the United States died from opioid-related overdoses.[14]

(g) "The CDC estimates the total economic burden of prescription opioid misuse in the [United States] is $78.5 billion a year, including the costs of health care, lost productivity, addiction treatment, and criminal justice involvement."[15]

(h) "During 2020, 28 states saw drug overdose deaths increase by more than 30 percent, amid the social isolation and economic stress of the pandemic."[16]

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[9] *7 Staggering Statistics About America's Opioid Epidemic*, ChoosePT, https://www.choosept.com/resources/detail/7-staggering-statistics-about-america-s-opioid-epi. [hereinafter, "*Stats*"].

[10] *Opioid Overdose Crisis*, National Institute on Drug Abuse, https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis [hereinafter, "*Crisis*"].

[11] *Id.*

[12] *Id.*

[13] *The Drug Overdose Epidemic: Behind the Numbers*, Centers for Disease Control and Prevention, https://www.cdc.gov/opioids/data/index.html.

[14] *Crisis*, supra note 10.

[15] *Stats*, supra note 9.

[16] *The Drug Overdose Toll in 2020 and Near-Term Actions for Addressing It*, The Commonwealth Fund, https://www.commonwealthfund.org/blog/2021/drug-overdose-toll-2020-and-near-term-actions-addressing-it.

(i) In fact, data released by the CDC "show[s] that drug overdose deaths reached a record high of 93,331 in 2020."[17] This is an increase of more than 20,000 deaths from 2019.

B. Opioid Use Disorder and Treatment

128. In 2017, the U.S. Department of Health and Human Services ("HHS") declared a public health emergency due to the widespread misuse and overdose-related deaths caused by opioids.

129. In 2017, to combat the epidemic, HHS issued over $800 million in grants to support the treatment and recovery of opioid addiction.

130. Between fiscal year 2016 and 2019, HHS provided more than $9 billion in grants to states tribes, and local communities to combat the opioid crisis.

131. This effort is showing some success, and Opioid Use Disorder treatment has spread throughout the United States.

132. There are currently more than 14,000 substance abuse facilities in the United States.

133. Additionally, there was a 4.1% decline in drug overdose deaths in the United States from 2017 to 2018.

134. This decrease is due, in large part, to increased access to effective and evidence-based treatment for Opioid Use Disorder.

135. One of the most effective treatments for individuals with Opioid Use Disorder is MAT.

136. Opioid Use Disorder treatment providers combine MAT with other modalities, such as behavioral therapy, as part of a comprehensive treatment plan.

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[17] *Id.*

137. Opioid Use Disorder treatment can be provided in a variety of settings, including inpatient, intensive outpatient, OTPs, and OBOT.

138. OTPs are treatment programs that dispense medication and provide counseling and other recovery support on-site.

139. OBOT refers to outpatient Opioid Use Disorder treatment provided in a setting other than a licensed OTP.

140. One of the most important aspects of OTPs and OBOT is group and/or individual therapy, which is provided in conjunction with MAT.

141. Three drugs are approved by the FDA for the treatment of Opioid Use Disorder: Methadone, Buprenorphine, and Naltrexone.

142. **Methadone** is administered daily as either a tablet or oral concentrate in order to control withdrawal symptoms and cravings.

143. Methadone is a synthetic opioid agonist that is used either for short periods of time to detoxify opioid users or for a longer period of time as maintenance therapy.

144. Some patients transition to Methadone from their opioid of choice and taper their dose to become opioid free while others take Methadone as a long-term, daily replacement in order to prevent withdrawal and relapse.

145. Methadone is generally dispensed daily by OTPs in order to prevent diversion, monitor a patient's response and any potential drug interactions, facilitate the provision of related services, such as individual and/or group therapy, and instill structure in the lives of individuals in recovery.

146. Many clinics do allow patients to earn "take home" privileges after a patient demonstrates compliance with her opioid treatment program.

147. Methadone is a Schedule II controlled substance, which means it is subject to the strictest prescribing and handling requirements of all medications on the American market.

148. **Buprenorphine** is an opioid that is used to treat Opioid Use Disorder.

149. Buprenorphine is available in several formulations: a tablet or strip that is used under the tongue (i.e., sublingual) or in the cheek (i.e., buccal), an intravenous or subcutaneous injection, a skin patch, or an implant.

150. Sublingual/buccal Buprenorphine is the most common formulation, either as a standalone substance (i.e., Subutex) or in combination with naloxone (i.e., Suboxone).[18]

151. Unlike Methadone, patients must wait a defined period of time prior to starting Buprenorphine, as its high binding affinity to certain opioid receptors can displace other opioids with lower binding affinities, which precipitates acute opioid withdrawal in the user.

152. Therefore, patients typically go through Buprenorphine induction under the supervision of a medical professional.

153. Buprenorphine can be dispensed by OTPs or prescribed by healthcare providers as a part of OBOT.

154. Buprenorphine is a Schedule III controlled substance.

155. **Naltrexone** (Brand Name: Vivitrol) is an extended-release injectable suspension, which is administered in an intramuscular injection.

156. Naltrexone is an opioid antagonist, which means that it blocks the activation of opioid receptors.

[18] Naloxone is an opioid antagonist with a high bioavailability when injected that is combined with Buprenorphine to discourage intravenous abuse. Naloxone will put an individual into acute opioid withdrawal if the formulation is injected.

157. Therefore, rather than controlling withdrawal symptoms and cravings, it prevents a user from achieving euphoria or other positive effects when using an opioid.

158. Naltrexone is generally administered approximately every four weeks.

C. Medicare

159. In 1965, Congress enacted the Medicare program under Title XVIII of the Social Security Act, creating the federal health insurance program for Americans 65 years or older, certain individuals with disabilities, and those afflicted with end-stage renal disease.

160. Medicare is funded through trust fund accounts held by the U.S. Treasury and supported by American taxpayers.

161. The Secretary of HHS has overall responsibility for the administration of Medicare. Within HHS, the responsibility for the administration of Medicare has been delegated to the Centers for Medicare & Medicaid Services ("CMS").

162. Health care providers must have a National Provider Identifier ("NPI") number prior to enrolling in Medicare.

163. Federal statutes and regulations require providers and suppliers to comply with and be knowledgeable of applicable regulations, statutes, and guidelines in order to be reimbursed by Medicare. 42 C.F.R. § 424.516(a)(1), (2).

164. Medicare only covers medically necessary items or services, excluding from coverage "any expenses incurred for items or services [...] which [...] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

165. In order to submit a claim to Medicare, institutional providers (including hospitals and freestanding OTP facilities) use the CMS Form 1450 claims form or the electronic equivalent.

166. The Form 1450 requires the provider to, *inter alia*, detail patient information, insurance information, date of treatment, provider information, and other relevant information to the patient's treatment and claim.

167. The back of the Form 1450 states: "Submission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate and complete . . . [and] [t]hat the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts."

168. Additionally, the back of the Form 1450 states, in bold print: **"THE SUBMITTER OF THIS FORM UNDERSTANDS THAT MISREPRESENTATION OR FALSIFICATION OF ESSENTIAL INFORMATION AS REQUESTED BY THIS FORM MAY SERVE AS THE BASIS FOR CIVIL MONETARY PENALTIES AND ASSESSMENTS AND MAY UPON CONVICTION INCLUDE FINES AND/OR IMPRISONMENT UNDER FEDERAL AND/OR STATE LAW(S)."**

169. Similarly, professional providers submit claims to Medicare on the HCFA 1500 claims form ("Form 1500").

170. The Form 1500 requires the provider to, *inter alia*, detail patient information, insurance information, date of treatment, provider information, and other relevant information to the patient's treatment and claim.

171. The back of the Form 1500 states, in bold print, **"Notice: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."**

172. The Form 1500 requires the signature of the physician or provider of the medical

or surgical services.

173. By signing the Form 1500, the provider "certif[ies] that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations."

174. As Medicare providers, Defendants are obligated to understand and certify their compliance with all applicable Medicare laws, regulations, and program instructions as a condition of payment of Medicare reimbursements.

175. Healthcare providers are prohibited from knowingly presenting or causing to be presented claims that represent a pattern of items or services that the person knew or should have known were not medically necessary, or knew or should have known were false or fraudulent. 42 U.S.C. §§ 1320a-7a(a)(1); 1320a-7(b)(7) (permitting exclusion of providers for the foregoing violations).

1. Opioid Treatment Programs, SAMHSA Certification, and Accreditation

176. Federal law sets forth detailed treatment standards for OTPs, including a requirement that counseling and other nondrug services be provided.[19] *See* 42 C.F.R. § 8.12.

177. Under 42 C.F.R. § 8.11, an OTP "must be the subject of a current, valid certification from SAMHSA to be considered qualified . . . to dispense opioid drugs in the treatment of opioid use disorder."

[19] In fact, in light of the COVID-19 pandemic, the regulations have been amended to facilitate counseling by video or phone when face-to-face counseling is not safe. *See* 42 C.F.R. §§ 410.67(b)(3), (4).

178. SAMHSA is the abbreviation for the Substance Abuse and Mental Health Services Administration.

179. SAMHSA is a governmental agency that is a branch of HHS. SAMHSA "leads public health efforts to advance the behavioral health of the nation."[20]

180. SAMHSA's "mission is to reduce the impact of substance abuse and mental illness in America's communities."[21]

181. In order to participate in the Medicare program and receive the bundled billing rates described below, an OTP must: (1) Be enrolled in the Medicare program; (2) have in effect a certification by SAMHSA for the OTP; (3) be accredited by an accrediting body approved by SAMHSA; and (4) have in effect a provider agreement with CMS.

182. In order to obtain SAMHSA certification, "an OTP must meet the Federal opioid treatment standards in [42 C.F.R.] § 8.12, must be the subject of a current, valid accreditation by an accreditation body or other entity designated by SAMHSA, and must comply with any other conditions for certification established by SAMHSA." *Id.* § 8.11(a)(2).

183. The SAMHSA certification application must contain a statement that the OTP will, *inter alia*, "operate in accordance with Federal opioid treatment standards and approved accreditation elements." *Id.* §§ 8.11(b)(6), (f)(7).

184. Compliance with these standards is, thus, an express condition for SAMHSA certification. *See id.* § 8.11(f)(7).

185. 42 C.F.R. § 8.12 provides an extensive list of Federal opioid treatment standards.

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[20] *About Us*, SAMHSA, https://www.samhsa.gov/about-us.

[21] *Id.*

186. The following is non-exhaustive list of those administrative, recordkeeping, and counseling requirements that must be provided by an OTP to obtain, and maintain, its certification (and, as detailed below, its participation in Medicare):

(a) "An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations." *Id.* § 8.12(b).

(b) "Each person engaged in the treatment of opioid use disorder must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions." *Id.* § 8.12(d).

(c) "OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients." *Id.* § 8.12(f)(1).

(d) "OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress." *Id.* § 8.12(f)(5)(i).

(e) "OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid use disorder." *Id.* § 8.12(g)(1).

187. Each patient accepted for treatment at an OTP must first be assessed initially and periodically throughout her treatment "to determine the most appropriate combination of services and treatment. *Id.* § 8.12(f)(4).

188. "The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical psychosocial, economic, legal, or other supportive services that a patient needs." *Id.*

189. "The treatment plan also must identify the frequency with which these services are to be provided." *Id.*

190. The treatment plan must be reviewed and updated to reflect the patient's evolving needs.

191. For example, a patient's treatment plan may provide that she is to receive group therapy once per week during the first six months of her treatment. In that case, an OTP must maintain records demonstrating that that the group therapy was provided. Complying with the terms of that treatment plan would be an express condition of the provider's SAMHSA certification and OTP status, and submission of any claims for treatment for that patient would contain an express and/or implied certification that the provider was eligible for payment under the Medicare Program.

192. In addition to SAMHSA certification, OTPs must be accredited by an accrediting body approved by SAMHSA.

193. SAMHSA has approved at least six accrediting bodies in order to "ensure that OTPs meet specific, nationally accepted standards for providing [MAT] . . . .": (1) CARF International; (2) Council on Accreditation; (3) The Joint Commission; (4) Missouri Department of Mental Health, Division of Behavioral Health; (5) National Commission on Correctional Health Care; and (6) Washington State Department of Health, Health Services Quality Assurance.[22]

194. Upon information and belief, these accrediting bodies require OTP providers to implement, *inter alia*, policies and procedures for regulatory compliance, treatment plans for individual patients, and services in addition to the simple administration of MAT.

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[22] *Approved Accreditation Bodies*, SAMHSA, https://www.samhsa.gov/medication-assisted-treatment/become-accredited-opioid-treatment-program/approved-accreditation-bodies.

195. Put differently, the accrediting agencies require OTP providers to do more than simply administer Methadone, Buprenorphine, and Naltrexone.

196. As detailed below, Defendants, acting in concert with one another, represent to governmental payors that they comply with the Federal opioid treatment standards set forth in 42 C.F.R. § 8.12 and are in compliance with the SAMHSA certification and accreditation requirements.

197. However, upon information and belief, Defendants' false and fraudulent conduct violates their SAMHSA certification and accreditation, the Federal OTP standards, and their provider agreements with CMS.

2. The SUPPORT Act and Bundled Billing

198. In 2018, Congress passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the "SUPPORT Act").

199. In response, CMS promulgated a rule which implemented certain provisions of the SUPPORT Act and changed the way that Medicare covers opioid treatment.

200. The rule would have permitted providers to bill for bundled services.

201. Put differently, rather than billing for individual services provided under various parts of Medicare, providers would be permitted to bill for a bundle of services on a weekly basis.

202. When promulgating the proposed rules and regulations applicable to bundled billing, CMS assumed that a typical patient would receive "one substance use counseling session, one individual therapy session, and one group therapy session per week and one toxicology test per month." 84 F.R. 62568-01, 62641 (Nov. 15, 2019).

203. Under this initial proposal, providers would only be able to bill Medicare for a bundle of treatment services, like the group of services listed above, if the beneficiary received at least 51% of the services in the patient's treatment plan. *See id.*

204. Many commenters—i.e., providers—stated that "it would be cumbersome to implement and would require far more frequent updating of the treatment plan than is typical, especially since the frequency of services delivered car vary significantly from week to week." *Id.*

205. CMS responded by stating: "In the interest of combating the opioid crisis and in the best interest of beneficiaries our goal is to minimize barriers to OTPs enrolling in Medicare and beginning to furnish services to Medicare beneficiaries." *Id.* at 62642.

206. Therefore, rather than requiring at least 51% of the services in a beneficiary's treatment plan be provided, CMS adopted a rule that only required one opioid use disorder treatment service be provided during a weekly episode of care in order to bill Medicare for the entire bundle of services.

207. CMS emphasized, however, that it would "be monitoring for abuse given this lower threshold for billing for full weekly bundled payment." *Id.* (emphasis added).

208. One of the most important safeguards to preventing fraud is ensuring that providers comply with the SAMHSA certification and accreditation requirements and the Federal OTP requirements outlined above.

209. While CMS permits providers to bill for a bundle of services without necessarily providing a majority of the services every week, the regulatory requirements that OTPs are required to abide by—namely the OTP regulations and SAMHSA certification and accreditation—*already* require that counseling and other services in a patient's treatment be provided as a precondition to a provider even participating in Medicare.

210. The bundled payment system discussed above has now been codified in the Code of Federal Regulations.

211. As of January 1, 2020, the SUPPORT Act requires that CMS pays a bundled payment rate for Opioid Use Disorder treatment services furnished by an OTP to individuals. *See* 42 C.F.R. § 410.67(d).

212. The regulation defines an Opioid Use Disorder treatment service to include one of the following items or services:

> (1) Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration . . . for use in treatment of opioid use disorder.
>
> (2) Dispensing and administration of opioid agonist and antagonist treatment medications, if applicable.
>
> (3) Substance use counseling by a professional to the extent authorized under State law to furnish such services including services furnished via two-way interactive audio-video communication technology as clinically appropriate, and in compliance with all applicable requirements. During a Public Health Emergency . . . where audio/video communication technology is not available to the beneficiary, the counseling services may be furnished using audio-only telephone calls if all other applicable requirements are met.
>
> (4) Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law), including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During a Public Health Emergency . . . where audio/video communication technology is not available to the beneficiary, the therapy services may be furnished using audio-only telephone calls if all other applicable requirements are met.
>
> (5) Toxicology testing.
>
> (6) Intake activities, including initial medical examination services . . . and initial assessment services . . . .
>
> (7) Periodic assessment services . . . that are furnished during a face-to-face encounter, including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During the Public Health Emergency . . . in cases where a beneficiary

does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

(8) Opioid antagonist medications that are approved by the Food and Drug Administration . . . for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication.

42 C.F.R. § 410.67(b).

213. An OTP must furnish "[a]t least one OUD treatment service" described in paragraphs (1) through (5) of the above list in order to submit a bill for the bundled payment.

214. The regulation outlines two types of bundled payments: (1) a "bundled payment for episodes of care in which a medication is provided"; and (2) "a bundled payment for episodes of care in which no medication is provided . . . ." *Id.* § 410.67(d)(2).

215. When a drug is provided, the bundled payment rate is heavily based on the drug component of the treatment provided in combination with the payment rate for the nondrug component of services. *See id.* § 410.67(d)(2).

216. CMS priced this bundle based on the "sum" of: (A) the physician fee schedule rates for psychotherapy (30 minutes with patient), group psychotherapy, alcohol and/or substance abuse assessment and intervention at the non-physician rate, (if applicable) injectable medication administration, and (if applicable) the insertion, removal, or insertion and removal of an implantable medication; (B) the average dispensing fees for oral medication "under state Medicaid programs" (if applicable); and (C) one-fourth of the 2019 clinical lab fee schedule for a presumptive and definitive drug test. *Id.* § 410.67(d)(2)(ii).

217. This rate is based on a weekly bundle of services, known as an "episode of care." *See id.* § 410.67(b).

218. Upon information and belief, at Defendant ATS's facilities, the weekly session goes Wednesday to Wednesday.

219. If an OTP furnishes services, but does not provide a drug during the partial episode, CMS requires a no-drug partial code to be used.

220. However, the same non-drug component rate set forth above is used in determining the rate. *See id.* § 410.67(d)(2)(iii).

221. If a patient requires more counseling, including individual or group therapy, than the amount in the plan or bundle, then the OTP can bill Medicare for add-on codes to increase the amount of payment it receives in the bundled payment rate. *See id.* § 410.67(d)(4)(i)(A).

222. The codes that are used by Medicare for bundled OTP services include G2067, G2068, G2069, G2070, G2071, G2072, G2073, G2074, and G2075. The following is a list of each code and the payment amount for the drug and nondrug portion of the bundled payment.

(a) HCPCS code G2067: Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
   - **Drug Cost:** $37.38
   - **Nondrug Cost:** $174.62
   - **Total Cost:** $212.00

(b) HCPCS code G2068: Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
   - **Drug Cost:** $81.08
   - **Nondrug Cost:** $174.62
   - **Total Cost:** $255.70

(c) HCPCS code G2069: Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
   - **Drug Cost:** $1,638.92

- **Nondrug Cost:** $181.15
- **Total Cost:** $1,820.07

(d) HCPCS code G2070: Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).

- **Drug Cost:** $4,547.13
- **Nondrug Cost:** $413.57
- **Total Cost:** $4,960.70

(e) HCPCS code G2071: Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).

- **Drug Cost:** $0
- **Nondrug Cost:** $433.30
- **Total Cost:** $433.30

(f) HCPCS code G2072: Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).

- **Drug Cost:** $4,547.13
- **Nondrug Cost:** $635.75
- **Total Cost:** $5,182.88

(g) HCPCS code G2073: Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).

- **Drug Cost:** $1,228.91
- **Nondrug Cost:** $181.15
- **Total Cost:** $1,410.06

(h) HCPCS code G2074: Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).

- **Drug Cost:** $0
- **Nondrug Cost:** $163.97
- **Total Cost:** $163.97

(i) HCPCS code G2075: Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).[23]

223. Largely, which code is billed depends on the type of drug that was given to the patient.

224. While the drug cost significantly outsizes the nondrug cost for injectable and implantable MAT drugs, the nondrug cost is higher for the two most commonly prescribed MAT drugs—oral methadone and oral buprenorphine.

225. Defendants are paid for OTP services by Medicare under these "bundled" codes.

D. Medicaid

226. The Medicaid Program is a health insurance program for low-income individuals and families and is jointly funded by the federal government and states, including the State of North Carolina.

227. States are not required to participate in the Medicaid program, but if they choose to, they must abide by the Medicaid requirements.

228. In order to be eligible for federal assistance under the Medicaid program, a state must have a plan for medical assistance that has been approved by the Secretary of HHS. 42 U.S.C. § 1396a(a).

229. When the Secretary of HHS approves a state's plan, the state then administers the various medical assistance programs under the Medicaid umbrella and the federal government provides grants to the state to reimburse them for medical services provided. *Id.*

[23] This Code is a placeholder for new drugs that are not specified in existing codes. Therefore, there is no fixed cost associated with the Code at this time.

230. The federal government pays states for a specified percentage of program expenditures, determined by the Federal Medical Assistance Percentage ("FMAP"). CMS also helps to administer this program.

231. Before providers may submit claims, DHHS requires that providers satisfy an enrollment process.

232. Providers enrolled in Medicaid must follow all Medicaid guidelines.

233. On information and belief, providers must certify that they are complying with all Medicaid guidelines and regulations when claims are submitted for payment.

1. Medicaid Coverage for Opioid Use Disorder and Treatment

234. Medicaid provides health coverage for individuals with Opioid Use Disorder.

235. The Affordable Care Act expanded Medicaid coverage for addiction treatment.

236. Additionally, many states further expanded Medicaid coverage in 2019 for behavioral health services, such as mental health and substance abuse.

237. To combat the opioid epidemic and in an effort to increase the availability of Medicaid benefits for addiction treatment, many states reduced administrative utilization controls.

238. On December 30, 2020, CMS issued a State Health Official letter, SHO# 20-005, which outlined the changes in federal law related to Medicaid's provision of MAT and coverage of OTP-related services.

239. The introductory paragraph to the letter states: "To increase access to medication-assisted treatment (MAT) for opioid use disorders (OUD), section 1006(b) of the SUPPORT Act requires states to provide Medicaid coverage of certain drugs and biological products, and related counseling services and behavioral therapy."[24]

[24] https://www.medicaid.gov/federal-policy-guidance/downloads/sho20005.pdf.

240. These changes were reflected in the Medicaid statutes.

241. For example, 42 U.S.C. § 1396(ee)(1) defines MAT to mean: **(A)** "all drugs approved under section 355 of Title 21, including methadone, and all biological products licensed under section 262 of this title to treat opioid use disorders; and **(B)** includes, with respect to the provision of such drugs and biological products, counseling services and behavioral therapy."

242. Thus, Medicaid Programs are now required to cover MAT services, including medication, counseling services, and behavioral therapy.

243. CMS's SHO letter includes the following mandate:

> To address the full scope of patients' treatment needs, section 1905(ee)(1) defines the required MAT benefit as including counseling services and behavioral therapy related to the drugs and biologicals covered under the new mandatory benefit. While states have flexibility to specify which counseling services and behavioral therapy they will include in the new mandatory benefit, states that already cover MAT successfully often cover a range of effective behavioral health services for beneficiaries with OUD receiving MAT, including the following:
>
> - Individual/Group Therapy generally helps patients identify treatment goals and potential solutions to problems that cause emotional stress; seeks to restore communication and coping skills; strengthens self-esteem; and promotes behavior change and optimal mental health. Cognitive behavioral therapy is a type of therapy that has been shown to be successful in treating individuals with OUD.
>
> - Peer Support Services are typically understood to be services in which a qualified peer support provider (also called a recovery coach or peer recovery support specialist) assists individuals with their recovery from substance use disorders, including OUD. Peer support services can also be offered in relation to co-occurring mental disorders and OUD. Services can include counseling on coping with symptoms and navigating early stages of the recovery process; modeling appropriate behavior, skills, and communication; engagement with a supportive community of recovering peers; and helping the person access community resources. CMS has issued guidance that addresses requirements for peer support providers.
>
> - Crisis Intervention Services are typically provided to immediately reduce or eliminate the risk of physical or emotional harm. Services can include evaluation, triage, and access to services, and treatment to effect symptom

reduction, harm reduction, and/or safe transition of individuals in acute crisis to the appropriate level of care for stabilization.[25]

244. The SHO letter also stated that "Federal regulation requires patients who receive treatment in an OTP to receive access to medical counseling, vocational, educational, and other assessment and treatment services, in addition to prescribed medication."[26]

2. North Carolina Medicaid

245. NC Department of Health and Human Services ("NC DHHS") manages the Medicaid program in North Carolina.

246. There are approximately two million Medicaid beneficiaries in North Carolina.

247. NC DHHS provides coverage for OTP services, OBOT, and other Opioid Use Disorder treatments.

248. NC DHHS provides coverage for individual and group therapy for individuals with Opioid Use Disorder.

249. On April 25, 2019, CMS notified NC DHHS that its proposed Substance Use Disorder ("SUD") protocol was approved.[27]

250. That protocol includes coverage for individuals receiving office-based OTP services.[28]

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[25] *Id.* at 4.

[26] *Id.* at 6.

[27] https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nc/Medicaid-Reform/nc-medicaid-reform-demo-sud-imp-plan-prtcl-20190425.pdf.

[28] *See id.* at 19 ("Outpatient opioid treatment is a service designed to offer the enrollee an opportunity to effect constructive changes in his or her lifestyle by receiving, via a licensed OTP, methadone or other drugs approved by the FDA for the treatment of an OUD, in conjunction with rehabilitation and medical services. North Carolina Medicaid covers methadone- and buprenorphine-assisted treatment at this service level.").

251. This protocol was enacted as NC Medicaid Clinical Coverage Policy 1A-41 ("the Policy").[29]

252. It does not appear that NC DHHS has issued a formal protocol or policy implementing the SUPPORT Act's requirements that OTP services be provided.

253. However, because the State of North Carolina participates in the Medicaid Program, it was required to start covering OTP services no later than October 2020 absent an exception from HHS.

254. Upon information and belief, the State of North Carolina is currently complying with the SUPPORT Act's mandate that Medicaid cover OTP services and has not received an exception from the Secretary of HHS.

255. NC DHHS covers the "procedure[s], product[s], or service[s] related to this policy when medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;

b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and

c. [t]he procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider."[30]

256. The Policy further states that it covers Office Based Opioid Treatment ("OBOT") services when **all** the following components are met: diagnosis and initial evaluation, initial

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[29] https://files.nc.gov/ncdma/documents/files/1A-41_6.pdf.
[30] *Id.* at 5.

laboratory testing, psychosocial treatment modalities, informed consent, treatment plan, treatment contract, and prescription drug monitoring."[31]

257. The Policy contains detailed requirements for each of these categories of treatment/services.

258. For example, NC Medicaid "require[s] a minimum of once monthly individual or group therapy sessions during the induction and stabilization phases of treatment conducted by a behavioral health professional licensed to treat substance use disorders . . . ."[32]

259. The Policy also requires that providers create an individualized treatment plan for beneficiaries.

260. Importantly, the Policy differentiates between OBOTs and OTPs, and makes clear that an OTP is a higher level of care that is subject to the Federal requirements outlined above—i.e., SAMHSA certification, accreditation by a SAMHSA accrediting body, and compliance with all Federal OTP regulations.

261. In order to bill Medicaid for OBOT or OTP services, providers (both physicians and non-physicians) must complete a certification process through NCTracks to become "Medicaid certified."

262. As part of this process, providers must also complete training on fraud, waste, and abuse.

263. Claims for payment by Medicaid are processed either by NCTracks or through Local Management Entities – Managed Care Organizations ("LME-MCOs").

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[31] *Id.* at 6.

[32] *Id.* at 8.

264. MAT provided through opioid treatment clinics (like those owned and operated by Defendants) are submitted through NCTracks.

265. Medicaid also directly contracts with LME-MCOs to manage the care of Medicaid beneficiaries who receive services for substance use disorders and mental health.

266. Behavioral health treatment provided through opioid treatment clinics (like those owned and operated by Defendants) is submitted through these LME-MCOs.

267. Upon information and belief, Defendants have contracts with NC DHHS and LME-MCOs.

268. Upon information and belief, the contracts provide, among other things, that Defendants will comply with federal and state laws, including the federal False Claims Act and the North Carolina counterpart, and regulations concerning the provision or billing of Medicaid-reimbursable or State-funded services.

VI. DEFENDANTS' FRAUDULENT SCHEME

269. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

A. Defendants' Eligibility to Provide Opioid Treatment Programs Under Medicare and Medicaid

270. In order to participate in the Medicare program and receive the bundled billing rates described below, an OTP must: (1) Be enrolled in the Medicare program; (2) have in effect a certification by SAMHSA for the OTP; (3) be accredited by an accrediting body approved by SAMHSA; and (4) have in effect a provider agreement with CMS.

271. Upon information and belief, Defendants are enrolled in the Medicare Program.

272. Upon information and belief, Defendants CRC and ATS submit bills to Medicare at the direction of Defendant Acadia in order to receive payment for OTP services provided to

Medicare beneficiaries.

273. Upon information and belief, Defendants, working in coordination with one another, applied for and received SAMHSA certifications for Defendant CRC's North Carolina facilities, including the Asheville facility and the North Wilkesboro facility.

274. Upon information and belief, Defendants, working in coordination with one another, applied for and received accreditation by a SAMHSA-approved accrediting body—CARF International.

275. Defendant ATS's Asheville facility and North Wilkesboro facility both have a three-year accreditation through CARF.

276. Upon information and belief, Defendants have Provider Agreements with CMS to provide services to Medicare beneficiaries.

277. Upon information and belief, Defendants submit claims for OTP services to Medicare using a Form 1500 and/or Form 1450.

278. Upon information and belief, these claims are paid by Medicare based on the implied and express certifications that Defendants make when submitting claims.

279. Similarly, upon information and belief, Defendants have provider contracts with NC DHHS and LME-MCOs so that they may submit claims for payment to North Carolina's Medicaid Program for MAT, OBOT, and/or OTP services.

280. Upon information and belief, these claims are paid by North Carolina Medicaid based on the implied and express certifications that Defendants make when submitting claims.

281. Pursuant to CMS's OTP Medicare Billing and Payment Fact Sheet, Medicare is the primary payor for OTP services for dually eligible beneficiaries (i.e., patients who have Medicare and Medicaid coverage) who previously received OTP services through Medicaid.

282. Upon information and belief, the claims submitted by Defendants for dually eligible beneficiaries are paid by Medicare, as a primary payor, and Medicaid, as a secondary payor, based on the implied and express certifications that Defendants make when submitting claims.

B. Defendants' Involvement with Government Healthcare Programs and Prior Fraud

283. Defendant Acadia has expressed concerns that these governmental programs do not generate sufficient revenue.

284. In its February 26, 2021, Form 10-K filing, the first "Financial Risk" that Acadia listed was: "Our revenue and results of operations are significantly affected by payments received from the government and third-party payors." Specifically, Acadia stated:

> Government payors in the U.S., such as Medicaid, generally reimburse us on a fee-for-service basis based on predetermined reimbursement rate schedules. As a result, we are limited in the amount we can record as revenue for our services from these government programs, and if we have a cost increase, we typically will not be able to recover this increase. In addition, the federal government and many state governments, are operating under significant budgetary pressure, and they may seek to reduce payments under their Medicaid programs for services such as those we provide. Government payors also tend to pay on a slower schedule. In addition to limiting the amounts they will pay for the services we provide their members, government payors may, among other things, impose prior authorization and concurrent utilization review programs that may further limit the services for which they will pay and shift patients to lower levels of care and reimbursement. Therefore, if governmental entities reduce the amounts they will pay for our services, or if they elect not to continue paying for such services altogether, or if a total or partial repeat of [the Affordable Care Act] results in significant contraction of the number of individuals covered by state Medicaid programs, our business, financial condition or results of operations could be adversely affected. In addition, if governmental entities slow their payment cycles further, our cash flow from operations could be negatively affected.[33]

285. Defendant Acadia, Defendant CRC, and Defendant CRC's predecessor, CRC Health Corp., have reached settlements with the United States for healthcare fraud.

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[33] 10-K, supra note 2, at 20.

286. On April 16, 2014, the Department of Justice announced a $9.25 million False Claims Act settlement with CRC Health Corp.[34]

287. The settlement related to "allegations that CRC knowingly submitted false claims by providing substandard treatment to adult and adolescent Medicaid patients suffering from alcohol and drug addiction at its facility in Burns, Tenn."[35]

288. The Burns, Tennessee facility was called New Life Lodge.

289. The Department of Justice Press Release states: "The government alleged that, between 2006 and 2012, New Life billed the Tennessee Medicaid program (TennCare) for substance abuse therapy services that were not provided or were provided by therapists who were not properly licensed by the state of Tennessee."[36]

290. Upon information and belief, CRC Health Corp. is the predecessor to Defendant CRC.

291. This settlement was announced approximately six months prior to Defendant Acadia's acquisition of CRC Health Corp.

292. Upon information and belief, Defendant Acadia and Defendant CRC now own and operate the New Life Lodge.

293. In May 2019, the Department of Justice announced a $17 million healthcare fraud settlement with Defendant Acadia and Defendant CRC.

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[34] *Tennessee Substance Abuse Treatment Facility Agrees to Resolve False Claims Act Allegations for $9.25 Million*, United States Department of justice (April 16, 2014), https://www.justice.gov/opa/pr/tennessee-substance-abuse-treatment-facility-agrees-resolve-false-claims-act-allegations-925.

[35] *Id.*

[36] *Id.*

294. Upon information and belief, this was the largest healthcare fraud settlement in the history of West Virginia ("the 2019 Settlement").

295. According to a Department of Justice Press Release, the 2019 Settlement addressed the following conduct:

> From January 1, 2012 to July 31, 2018, Acadia's treatment centers sent urine and blood samples to an outside laboratory, San Diego Reference Laboratory (the "San Diego Lab") for all moderate and high complexity drug testing. The San Diego Lab performed the testing and invoiced Acadia's treatment centers for the services, and did so at the request of the treatment centers. Acadia's treatment centers paid the San Diego Lab directly. However, Acadia's West Virginia treatment centers then billed West Virginia Medicaid for the urine and blood testing performed by the San Diego Lab, as though the testing had been performed by the treatment centers. In the claims for reimbursement submitted to Medicaid, Acadia's treatment centers represented that they had performed the moderate and/or high complexity laboratory services. Medicaid, induced by the claims submitted by Acadia's treatment centers, paid the treatment centers a substantially higher amount than the San Diego Lab charged to actually perform the testing. Medicaid regulations and policies specifically prohibited Acadia's treatment centers from seeking reimbursement for moderate and complex urine and blood testing which they were not certified to perform, and did not, in fact, perform.
>
> Medicaid paid Acadia's treatment centers $8,500,000 as a result of these moderate and complex urine and blood testing claims, resulting in a loss of $2,181,100 to the State of West Virginia and $6,318,900 to the United States. . . . As a result of the $17 million settlement, which represents twice the actual loss suffered by Medicaid, both the state and federal programs will be made whole.[37]

296. As part of the 2019 Settlement, Defendant Acadia and its subsidiary, Defendant CRC, entered into a five-year Corporate Integrity Agreement ("CIA") with HHS-OIG.[38]

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[37] *United States Attorney Announces $17 Million Healthcare Fraud Settlement*, United States Attorney's Office for the Southern District of West Virginia (May 6, 2019), https://www.justice.gov/usao-sdwv/pr/united-states-attorney-announces-17-million-healthcare-fraud-settlement.

[38] Corporate Integrity Agreement, https://oig.hhs.gov/fraud/cia/agreements/CRC_Heatlh_LLC_and_Acadia_Healthcare_Company_Inc_05032019.pdf [hereinafter "CIA"].

297. The CIA "applies to CRC Health, LLC and to Acadia in its oversight, operation, and management of CRC Health, LLC."[39]

298. The CIA requires Defendant Acadia to establish and maintain an extensive Compliance Program.

299. Within 90 days after the Effective Date[40] of the CIA, Defendant Acadia was required to appoint a Compliance Officer.

300. The Compliance Office is responsible for, "without limitation:

a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in th[e] CIA and with Federal health care program requirements;

b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Acadia (Acadia Board) and shall be authorized to report on such matters to the Acadia Board at any time. Written documentation of the Compliance Officer's reports to the Board shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by CRC as well as any reporting obligations created under th[e] CIA."[41]

301. The CIA required Defendant Acadia to appoint a Compliance Committee within 90 days after the Effective Date of the CIA.

302. The CIA also required Defendant Acadia to appoint a Board of Directors Compliance Committee ("Board Committee").

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[39] *Id.* at 1. Defendant Acadia and Defendant CRC are collectively referred to as "CRC" in the CIA.

[40] The Effective Date is the "date on which the final signatory of th[e] CIA executes th[e] CIA." *Id.* The final signatory signed the CIA on May 3, 2019. *Id.* at 31. Accordingly, and upon information and belief, the Effective Date of the CIA is May 3, 2019.

[41] *Id.* at 1–2.

303. The Board Committee is required to meet at least quarterly "to review and oversee CRC's compliance program . . . ."[42]

304. Additionally, the Board Committee is responsible for adopting an annual resolution, "signed by each member of the Board summarizing its review and oversight of CRC's compliance with Federal health care program requirements and the obligations of th[e] CIA."[43]

305. At a minimum, Defendant Acadia's Board resolution is required to include the following language:

> "The Board Committee has made a reasonable inquiry into the operations of CRC's Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board Committee has concluded that, to the best of its knowledge, CRC has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."[44]

306. The CIA also required certain employees of Defendant Acadia and Defendant CRC "to monitor and oversee activities within their areas of authority and . . . annually certify that the applicable CRC department is in compliance with applicable Federal health care program requirements and the obligations of th[e] CIA."[45]

307. At a minimum, "[t]hese Certifying Employees shall include . . . the following: Division CEO/President, Division CFO, Senior Vice President, Regional Vice Presidents, and Division Compliance Officer."[46]

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[42] *Id.* at 4.

[43] *Id.*

[44] *Id.*

[45] *Id.* at 5.

[46] *Id.*

308. These Certifying Employees are required to sign a certification every annual reporting period that states:

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and CRC policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of CRC is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."[47]

309. The CIA also required Defendant Acadia and Defendant CRC to "develop and implement written policies and procedures regarding the operation of its compliance program . . . and CRC's compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of th[e] CIA, CRC shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons."[48]

310. The CIA defines "Covered Persons" to include, *inter alia*, (a) "all contractors, subcontractors, agents, and other persons who furnished patient care items or services or who perform billing or coding functions on behalf of CRC, excluding vendors whose sole connection with CRC is selling or otherwise providing medical supplies or equipment to CRC" and (b) "all physicians and other non-physician practitioners who are members of CRC's active medical staff."[49]

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[47] *Id.*

[48] *Id.* at 6.

[49] *Id.* at 1–2.

311. Defendant ATS and its employees, agents, contractors, and subcontractors are "Covered Persons" under the terms of the CIA.

312. The CIA imposes training and education requirements for these "Covered Persons":

> Within 90 days after the Effective Date, CRC shall develop a written plan (Training Plan) that outlines the steps CRC will take to ensure that all Covered Persons receive at least annual training regarding CRC's CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute and the Stark Law. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. CRC shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.[50]

313. Defendant Acadia and Defendant CRC must "make available to OIG, upon request, training materials and records verifying that Covered Persons and Acadia Board members have timely received the training required under this section."[51]

314. Additionally, the CIA required Defendant Acadia and Defendant CRC to "develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with CRC's participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries."[52]

315. This risk assessment and internal review process requires Defendant Acadia and Defendant CRC to, at least annually: "(1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4)

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[50] *Id.* at 6.

[51] *Id.* at 7.

[52] *Id.* at 8.

develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans."[53]

316. The CIA also required Defendant Acadia and Defendant CRC to develop a Disclosure Program within 90 days after the Effective Date.

317. The Disclosure Program must include "a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with CRC's policies, conduct, practices or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law."[54]

318. Defendant Acadia and Defendant CRC must "appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas)."[55]

319. "The Disclosure Program also shall include a requirement that all of CRC's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by CRC."[56]

320. Upon receipt of a disclosure, the Compliance Officer or his or her designee must gather information from the individual making the disclosure and "make a preliminary, good faith

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[53] *Id.*

[54] *Id.*

[55] *Id.* at 8–9.

[56] *Id.* at 9.

inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted."[57]

321. The CIA also contains the following requirement: "For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, CRC shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted."[58]

322. The CIA requires the Compliance Officer or his or her designee to log every disclosure within two business days of receipt.

323. The CIA requires Defendant Acadia and Defendant CRC to notify HHS-OIG ("after a reasonable opportunity to conduct an appropriate review or investigation of the allegations") within 30 days of determining that a "Reportable Event" exists.[59]

324. The CIA defines a "Reportable Event" as: (a) a substantial overpayment; (b) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; (c) the employment of or contracting with a Covered Person who is an Ineligible Person as defined by [the CIA]; or (d) the filing of a bankruptcy petition by Defendant CRC.[60]

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[57] *Id.*

[58] *Id.*

[59] *Id.* at 12.

[60] *Id.*

325. When Defendant Acadia and Defendant CRC learn of a Reportable Event, they must report the event to HHS-OIG.

326. The report must include: (a) a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event; (b) a statement of the Federal criminal, civil, or administrative laws that are probably violated by the Reportable Event, if any; (c) the Federal healthcare programs affected by the Reportable Event; (d) a description of the steps taken by Defendant Acadia and Defendant CRC to identify and quantify any overpayments; and (e) a description of Defendant Acadia and Defendant CRC's actions taken to correct the Reportable Event and prevent it from recurring.[61]

327. Defendant Acadia and Defendant CRC must also submit a written report to HHS-OIG during each of the five years covered by the CIA. These annual reports must include, *inter alia*, a summary of all Reportable Events during the applicable year. Importantly, the annual report must also contain a certification by the Compliance Officer and Chief Executive Officer that: (a) to the best of his or her knowledge, except as otherwise described in the report, Defendant Acadia and Defendant CRC have implemented and is in compliance with all of the requirements of the CIA; (b) he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and (c) he or she understands that the certification is being provided to and relied upon by the United States.[62]

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[61] *Id.* at 13.

[62] *Id.* at 18–19.

328. Furthermore, the CIA permits HHS-OIG to "conduct interviews, examine and/or request copies of or copy CRC's books, records, and other documents and supporting materials, and conduct on-site reviews of any of CRC's locations, for the purpose of verifying and evaluating:" (a) Defendant Acadia and Defendant CRC's compliance with the CIA and (b) Defendant Acadia and Defendant CRC's compliance with the requirements of Federal healthcare programs.[63]

329. The CIA also provides for contractual remedies—including a range of stipulated monetary penalties—if Defendant Acadia and/or Defendant CRC breaches the terms of the CIA. These remedies are in addition to other damages and penalties available under Federal and State law.

330. Moreover, Defendant Acadia and Defendant CRC "agree[d] that a material breach of th[e] CIA by CRC constitutes an independent basis for CRC's exclusion from participation in the Federal health care programs."[64]

331. The CIA defines a "material breach" to include, *inter alia*, "a failure by CRC to report a Reportable Event, take correction action, or make the appropriate refunds," as required by the CIA.[65]

332. The CIA also defines a "material breach to include, *inter alia*, "repeated violations or a flagrant violation of any of the obligations under th[e] CIA . . . ."[66]

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[63] *Id.* at 21.

[64] *Id.* at 25–26.

[65] *Id.* at 25.

[66] *Id.*

333. The CIA states: "All requirements and remedies set forth in th[e] CIA are in addition to and do not affect (1) CRC's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements."[67]

334. In its February 26, 2021 10-K, Defendant Acadia emphasized the severe consequences of noncompliance with the requirements of the CIA:

> Material, uncorrected violations of the CIA could lead to our suspension or exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs and repayment obligations. In addition, we are subject to possible civil penalties for failure to substantially comply with the terms of the CIA, including stipulated penalties ranging between $1,000 to $2,500 per day. We are also subject to a stipulated penalty of $50,000 for each false certification made by us or on our behalf, pursuant to the reporting provisions of the CIA. The CIA increases the amount of information we must provide to the federal government regarding our healthcare practices and our compliance with federal regulations. The reports we provide in connection with the CIA could result in greater scrutiny by regulatory authorities.[68]

335. The 10-K and CIA demonstrate that Defendant Acadia and Defendant CRC are aware of their obligations under State and Federal law.

336. Under the terms of the CIA, Defendants have a contractual obligation to train Defendant ATS and its employees, agents, contractors, and subcontractors about the above requirements.

337. As detailed more fully below, Defendants and their employees, agents, contractors, and subcontractors failed to comply with the terms of the CIA.

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[67] *Id.* at 29.

[68] 10-K, supra note 2, at 30.

C. Opioid Use Disorder Services Provided by Defendants

338. At the clinics owned and operated by Defendants, patients are treated with Methadone, Buprenorphine, and/or Naltrexone as part of an OTP or through OBOT.

339. The Asheville facility treats patients with Methadone or Buprenorphine, but does not prescribe Naltrexone.

340. The Asheville facility has a patient census of approximately 176 patients.

341. At the Asheville facility, Relator's job is to handle physical assessments of patients and prescribe appropriate doses of Methadone and Buprenorphine.

342. Other providers at the clinics are supposed to handle counseling and medication storage and distribution.

343. Patients at Defendants' clinics are supposed to receive both MAT and behavioral health treatment, which includes group and/or individual counseling.

344. Patients' treatment plans indicate the frequency and type of counseling services that must be provided.

345. Defendants are paid for these OTP services by Medicare under the "bundled" codes described.

346. Additionally, upon information and belief, North Carolina Medicaid pays Defendants for MAT, OBOT, and/or OTP services.

347. At Defendants' clinics, patients must physically come into the clinic for their medications and/or prescriptions.

348. Because of the COVID-19 pandemic, patients can receive their counseling appointments by video or, if video is unavailable, by telephone.

349. When patients come into Defendants' facilities for their medication, they go to a "dosing window" and a nurse hands them their medication.

350. Patients who come to the clinic to pick up their medication typically only spend ten to fifteen minutes at the clinic.

351. How often patients come into the clinics for medication treatment depends on the patient and her treatment plan.

352. For example, at Defendants' facilities, how often patients come into the clinics for their medication depends on what "level" the patient is.

353. Generally, patients come into the clinic six days per week to get their medication.

354. Other patients have "earned" some take-home medication and need to come into the clinic two to three times per week to get their medication.[69]

355. "Level 5" patients come into the clinic once per week to get medication.

356. "Level 6" patients are seen in the clinic once every fifteen days for medication.

357. "Level 7" patients are seen in the clinic for medication dosing every twenty-eight days.

358. How often patients receive counseling therapy depends on the patient and whether they are new or established.

359. Established patients are supposed to receive counseling at least once per month at Defendants' clinics.

[69] The reason that take-home medication is "earned" is because the medication that is used to treat Opioid-Use Disorders carry a risk of abuse themselves.

360. New patients are supposed to be seen at least twice a month for counseling with clinic-contact at least every week. After 90 days, the patient would change to counseling at least once per month.

D. Defendants' Fraudulent Conduct and Falsification of Patient Records

361. Beginning in September 2020, Relator began noticing new fraudulent activity occurring at Defendants' Asheville facility.

362. The Asheville facility began documenting that they were doing group therapy, but they were not actually doing group therapy.

363. In fact, the Asheville facility has not held any group therapy sessions for approximately two years.

364. In approximately March 2021, Defendants began falsely documenting that they were performing a certain type of group therapy called "bibliotherapy."

365. Bibliotherapy is evidence-based therapy[70] where the therapist provides the patient with a book or article to read and then the patient comes back into the clinic to discuss what was read with the counselor.

366. Bibliotherapy can be done individually or as a group.

367. But it is only effective when there is interaction between patients, their peers, and/or therapists.

[70] While there is some evidence to support the use of bibliotherapy in opioid treatment programs, it is far from overwhelming. For example, the National Institute on Drug Abuse Research Abstract Database contains limited references to scientific studies involving bibliotherapy. The only available abstract discussed a study involving ten inmates in a Malaysian government-aided rehabilitation session. The study only examined six group counseling sessions with these ten individuals. Adb Hussin, *Reading to Recover: Exploring Bibliotherapy as a Motivational Tool for Recovering Addicts*, National Institute on Drug Abuse, https://www.drugabuse.gov/international/abstracts/reading-to-recover-exploring-bibliotherapy-motivational-tool-recovering-addicts.

368. When patients check-in at reception, the clinic gives the patients a handout to fill out during their visit.

369. These handouts are on various topics, including loneliness, forgiveness, and gas-lighting.

370. The handouts often contain pre-written text on the topics with clip-art pictures and blank lines for patients to respond to questions.

371. The clinic collects these handouts once the patient has completed the handout at the visit.

372. The clinic adds these handouts to the patient's file and medical records.

373. Upon information and belief, this handout is done to create a paper trail—to attempt to represent that group therapy was performed and that the information on the handout was used to facilitate a group discussion.

374. But no group therapy is actually performed.

375. At the Asheville clinic, starting no later than June 2021, Defendants began sending out emails with templates to make the creation of fraudulent group therapy notes easier.

376. At the beginning of each week, the clinical manager sends an email to the clinic staff with a template group therapy note that is to be used that week.

377. Defendants' staff then copy and paste the template group therapy note into individual group therapy notes for patients who picked up medications or had assessments on the same day.

378. Defendants' staff use the completed handouts to make the false group therapy notes look like an actual group therapy session happened.

379. In other words, Defendants create a lengthy patient note which discusses, in detail, group therapy sessions that never occur.

380. The patient notes are signed—often electronically—by Defendants' counselors.

381. Upon information and belief, Defendants engage in this fraudulent conduct to save time and money so that they can see more Medicare and Medicaid patients without taking the necessary time to provide meaningful counseling services.

382. In an attempt to conceal the fraudulent nature of these group therapy notes, the weekly emails discussed above often contained a disclaimer that this bibliotherapy was not intended to displace actual individual or group therapy.

383. For example, on July 19, 2021, a counselor sent an email to the Asheville facility's employees that contained the following introductory paragraph:

> The following is a worksheet provided to patients as part of a CBT approach utilizing bibliotherapy. The intent is to allow patients the opportunity to contemplate topics that may otherwise go unexplored in general counseling sessions. Each worksheet will be reviewed by the patient's counselor and aggregated into an individualized group note. This is intended as a tool to improve the therapeutic alliance by giving the patient time to contemplate and compose their response in a more intentional and less reactive way. In many cases the responses may be more transparent and display more vulnerability than under usual circumstances involving active observation. It is in this way the therapeutic alliance can be enriched while reducing the amount of time in which the patient needs to commit to in clinic visits. This is not meant to be a replacement for face-to-face or group sessions, but rather augment and inform those approaches while being conscientious of the risks that abound due to the COVID-19 Pandemic. It is recommended that each patient devote 45 minutes to the assignment.

384. Upon information and belief, the purpose of these clinic-wide emails with pre-populated group therapy notes was to avoid providing actual therapy to patients and to increase Defendants' revenue.

385. Despite Defendants' statement in the above email that the fraudulent bibliotherapy sessions were not meant to be a replacement for actual therapy, they were treated as a replacement for actual therapy.

386. Upon information and belief, Defendants knew about this process and implemented it as a policy in order to help their bottom line.

387. Upon information and belief, over time, Defendants have become more comfortable with less detailed, but still fraudulent, group therapy notes.

388. On July 6, 2021, the same counselor who sent the above email sent an email to the Asheville facility's employees with a group therapy note to be copied and pasted into false group therapy notes.

389. A short time later, the counselor sent a follow-up email telling the Asheville facility's employees to disregard the prior email and use a different false group therapy note.

390. The email clearly stated the reason for this clarification: "Corporate wants less detail."

391. Upon information and belief, this indicates that this method of falsifying group therapy records is a corporate policy that has been implemented in facilities owned and operated by Defendants across the country.

392. Additionally, upon information and belief, this email indicates that Defendants monitor the level of detail in the fraudulent group therapy notes.

393. Upon information and belief, including less detail in a false group therapy note saves time and money and allows Defendants to see more Medicare and Medicaid beneficiaries.

394. Upon information and belief, this conduct is still occurring at Defendants' facilities.

395. Relator has firsthand knowledge about how this fraudulent scheme operates in the Asheville facility.

396. For example, Patient 1 receives Methadone from the Asheville facility's OTP.

397. Patient 1's treatment plan states that he expressed interest in group therapy because it had been beneficial in the past.

398. Patient 1's treatment plan also stated that he could benefit from attending group therapy.

399. However, Patient 1's treatment plan did not state the frequency with which he should receive group therapy.

400. Patient 1 came to the Asheville, North Carolina clinic on May 19, 2021 to see Relator for an appointment for a physical assessment and for Relator to assess and review his current medications.

401. Patient 1 is a recipient of Medicare and Medicaid.

402. Patient 1 told Relator that he is asked to fill out the group therapy handout almost every time he comes into the clinic.

403. Patient 1 did not participate in any group therapy when he went to the Asheville facility on May 19, 2021.

404. In fact, Patient 1 told Relator that he has never participated in any group therapy at Defendants' facilities.

405. However, Patient 1's chart contains numerous group therapy notes, indicating that he received group therapy many times.

406. For example, Patient 1's chart contains detailed group therapy notes for several visits in April 2021.

407. These notes falsely state that Patient 1 participated in group therapy in the lobby of the Asheville facility.

408. The fraudulent group therapy notes further state that a "group leader" facilitated the lobby groups and are written in a narrative format that falsely states that there was an interactive therapy session led by a therapist.

409. One group therapy note, dated April 21, 2021, concludes by stating: "Each member of the group was thanked for their participation."

410. However, these group therapy sessions never occurred.

411. Upon information and belief, Defendants submitted claims to Medicare and Medicaid for Patient 1's OTP services in April and May 2021.

412. Upon information and belief, the United States and the State of North Carolina—unaware of the falsity of Defendants' certifications that they were complying with Federal law, State law, their SAMHSA certification and accreditation, their provider agreements, and the terms of the CIA—paid the claims for Patient 1's May 19, 2021 treatment and the April 2021 services that correlate with the dates of the falsified group therapy records.

413. Upon information and belief, Defendants follow the same process described above for other patients at its clinics.

414. The Medical Director of the North Wilkesboro facility told Relator that group therapy notes are also falsified at the North Wilkesboro facility and that she notified the Clinic Director about the fraud.

415. In March 2021, Relator told the Clinic Director of the Asheville facility, Jason Hines, that Defendants were creating fraudulent group therapy notes.

416. Mr. Hines told Relator that this conduct was occurring at other North Carolina locations, including Defendants' Pinehurst and Fayetteville locations.

417. Mr. Hines also told Relator that the Regional District Manager stated that Relator should "stay in her lane."

418. Upon information and belief, the Regional District Manager oversees Defendants' activities within North Carolina.

419. Relator informed Mr. Hines again in May 2021 and July 2021 that the fraudulent group therapy notes were still being created and used.

420. Upon information and belief, neither Mr. Hines nor the Regional District Manager took any corrective action to stop the fraud.

421. Upon information and belief, Mr. Hines' response, the Regional District Manager's warning to Relator, and the email, discussed above, with the corporate directive to provide less detail in the fraudulent group therapy notes indicates that this fraud is widespread across Defendants' facilities.

422. Upon information and belief, the conduct is occurring at Defendants' facilities across the State of North Carolina and across the United States, including but not limited to the following states: Alaska, Arizona, Arkansas, California, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

423. Relator also knows that Defendants do not always perform the required amount of individual therapy and counseling sessions required under patients' treatment plans and federal and state law.

424. During the COVID-19 pandemic, the Asheville facility began conducting non-contact individual therapy and/or counseling sessions.

425. Defendants made no attempt to ascertain whether patients had the ability to attend therapy and/or counseling sessions by video.

426. Instead, Defendants directed their employees in the Asheville facility to perform therapy and/or counseling solely by telephone.

427. Thus, staff at the Asheville facility will often call patients, have a brief phone call with them, and document the session as a full therapy session.

428. Frequently, no actual therapy and/or counseling occurs during the call.

429. Many patients receiving MAT, OBOT, and/or OTP services are not receiving any meaningful therapy from Defendants.

430. Instead, upon information and belief, Defendants provide inadequate individual therapy, no group therapy, and bill Medicare and Medicaid as if an entire suite of services are provided to its patients.

431. Federal and State law mandate therapy and counseling for a reason: It is necessary to ensure that patients with Opioid-Use Disorder receive meaningful treatment and do not relapse.

432. While MAT helps treat the physical cravings and withdrawal associated with opioid addiction, therapy and counseling are the only means to treat underlying trauma and unearth and treat the underlying reasons for addiction.

E. Defendants' Express and/or Implied False Certifications Under Federal OTP Regulations and Standards, North Carolina Law, SAMHSA Certifications, CARF Accreditations, and Provider Agreements

433. Defendants are in violation of Federal law and State law by failing to provide any meaningful therapy and/or counseling to MAT, OBOT, and/or OTP patients.

434. Defendants' scheme to falsity group therapy records violates the Federal OTP regulations and standards.

435. Upon information and belief, Defendants' failure to provide adequate counseling and/or therapy violates the Federal OTP regulations and standards.

436. Defendants' failure to properly document the frequency and type of therapy and/or counseling in patient treatment plans violates the Federal OTP regulations and standards.

437. Defendants' failure to determine whether patients have the ability to attend non-contact therapy and/or counseling sessions by video rather than telephone violates the Federal OTP regulations and standards.

438. Defendants' scheme to falsity group therapy records violates the State of North Carolina's MAT, OBOT, and OTP regulations and standards.

439. Upon information and belief, Defendants' failure to provide adequate counseling and/or therapy to patients violates the State of North Carolina's MAT, OBOT, and/or OTP regulations and standards.

440. Defendants' failure to properly document the frequency and type of therapy and/or counseling in patient treatment plans violates the State of North Carolina's MAT, OBOT, and/or OTP regulations.

441. Upon information and belief, Defendants' failure to determine whether patients have the ability to attend non-contact therapy and/or counseling sessions by video rather than telephone violates the State of North Carolina's MAT, OBOT, and/or OTP regulations.

442. Upon information and belief, Defendants' scheme to falsity group therapy records violates Defendants' SAMHSA certifications.

443. Upon information and belief, Defendants' failure to provide adequate counseling and/or therapy to patients violates Defendants' SAMHSA certifications.

444. Upon information and belief, Defendants' failure to properly document the frequency and type of therapy and/or counseling in patient treatment plans violates Defendants' SAMHSA certifications.

445. Upon information and belief, Defendants' scheme to falsity group therapy records violates Defendants' CARF accreditations.

446. Upon information and belief, Defendants' failure to provide adequate counseling and/or therapy to patients violates Defendants' CARF accreditations.

447. Upon information and belief, Defendants' failure to properly document the frequency and type of therapy and/or counseling in patient treatment plans violates Defendants' CARF accreditations

448. Upon information and belief, Defendants' scheme to falsity group therapy records violates Defendants' provider agreements.

449. Upon information and belief, Defendants' failure to provide adequate counseling and/or therapy to patients violates Defendants' provider agreements.

450. Upon information and belief, Defendants' failure to properly document the frequency and type of therapy and/or counseling in patient treatment plans violates Defendants' provider agreements.

451. Defendants' actions and failure to comply with these requirements constitutes a pattern or practice that necessarily leads to the submission of false claims to the United States and the State of North Carolina.

452. Compliance with these standards, contracts, laws, regulations, certifications, and accreditations are express and/or implied conditions of participation in the Medicare Program and the Medicaid Program.

453. Compliance with these standards, contracts, laws, regulations, certifications, and accreditations are express and/or implied conditions of payment for Medicare and Medicaid claims for MAT, OBOT, and/or OTP services.

454. The United States and the State of North Carolina, unaware of the falsity of these certifications, have processed and paid claims submitted to Medicare and Medicaid based on Defendants' certifications.

455. Defendants' express and/or implied false certifications as set forth above are material to Defendants' participation in the Medicare and Medicaid Program.

456. Defendants' express and/or implied false certifications as set forth above are material to the United States' and the State of North Carolina's payment decisions for Medicare and Medicaid claims for MAT, OBOT, and/or OTP services.

457. As a result, every Medicare or Medicaid claim submitted since at least September 2020 is a false claim.

F. Defendants' Express and/or Implied False Certifications Related to the CIA

458. On or about March 2021, Relator told the Clinic Director of the Asheville facility that Defendants were engaging in fraud by falsifying group therapy records.

459. On or about May 2021, Relator told the Clinic Director of the Asheville facility that Defendants were engaging in fraud by falsifying group therapy records.

460. On or about July 2021, Relator told the Clinic Director of the Asheville facility that Defendants were engaging in fraud by falsifying group therapy records.

461. Each of these constituted a "Reportable Event" under the terms of the CIA, and Defendants and their employees, agents, contractors, and subcontractors had a contractual obligation to report the fraudulent conduct to HHS-OIG.

462. Upon information and belief, Defendants knowingly failed to comply with that requirement in the CIA and are in material breach of the CIA.

463. Additionally, Defendants violated the CIA in several other ways.

464. Defendants did not provide Relator with annual training related to their obligations under the CIA.

465. Despite being the Assistant Medical Director at the Asheville facility, Relator was not provided any training related to Defendants' obligations under the CIA until May 2021.

466. Nor, upon information and belief, did Defendants provide Relator with any written policies and procedures regarding the operation of the Compliance Program required by the CIA.

467. Nor did Defendants provide Relator with, or publicize the existence of, information about a Disclosure Program until May 2021.

468. Upon information and belief, Defendants did not log Relator's disclosure of fraud.

469. Upon information and belief, Defendants did not investigate Relator's disclosure of fraud.

470. Upon information and belief, Defendants did not take any remedial actions to stop the fraud Relator reported.

471. Upon information and belief, Defendants did not implement or comply with policies and procedures designed to ensure adherence to the Compliance Program required by the CIA.

472. Upon information and belief, Defendants have signed the certifications and resolutions described above as required by the CIA.

473. These certifications, as required by the CIA, are express certifications that Defendants are complying with the terms of the CIA.

474. However, upon information and belief, Defendants have not actually performed the compliance activities or oversight required by the CIA.

475. Defendants' inaction and failure to comply with the terms of the CIA is a pattern or practice that necessarily leads to the submission of false claims to the United States and the State of North Carolina.

476. Compliance with the requirements of the CIA are express and/or implied conditions of participation in the Medicare Program and the Medicaid Program.

477. Compliance with the requirements of the CIA are express and implied conditions of payment for Medicare and Medicaid claims for MAT, OBOT, and/or OTP services.

478. The United States and the State of North Carolina, unaware of the falsity of these certifications, have processed and paid claims submitted to Medicare and Medicaid based on Defendants' certifications.

479. Defendants' express and/or implied false certifications related to the CIA are material to Defendants' participation in the Medicare and Medicaid Program.

480. Defendants' express and/or implied false certifications related to the CIA are material to the United States' and the State of North Carolina's payment decisions for Medicare and Medicaid claims for MAT, OBOT, and/or OTP services.

481. As a result, every Medicare or Medicaid claim submitted by Defendants since at least September 2020 is a false claim.

G. Stipulated Penalties Under the CIA

482. The CIA contains a provision stating that Defendant Acadia and Defendant CRC are "expected to fully and timely comply with all of [their] CIA obligations."[71]

483. Defendant Acadia and Defendant CRC agreed to Stipulated Penalties for various violations of the CIA.

484. Under the terms of the CIA, a Stipulated Penalty of $2,500 applies "for each day CRC fails to establish, implement or comply with" the following obligations:

a. a Compliance Officer;

b. a Compliance Committee;

c. the Board Committee compliance obligations;

d. the management certification obligations, and the development and implementation of a written process for Certifying Employees, as required by Section III.A.4;

e. written Policies and Procedures;

f. the development of a written training plan and the training and education of Covered Persons and Acadia Board members;

[71] CIA at 22.

g. a risk assessment and internal review process;

h. a Disclosure Program;

i. ineligible Persons screening and removal requirements;

j. notification of Government investigations or legal proceedings;

k. policies and procedures regarding the repayment of Overpayments; and

l. reporting of Reportable Events.[72]

485. The CIA lists seven other Stipulated Penalties that relate to failures to comply with certain requirements under the CIA.

486. The final listed Stipulated Penalty provision imposes "[a] Stipulated Penalty of $1,000 for each day CRC fails to comply fully and adequately with any obligation of the CIA."[73]

COUNT I
Violations of the FCA: Presenting or Causing the Presentation of False Claims
31 U.S.C. § 3729(a)(1)(A)

487. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

488. In pertinent part, the FCA establishes liability for "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).

489. Defendants knowingly or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, presented or caused to be presented false claims "for payment or approval" to the United States in violation of 31 U.S.C. § 3729(a)(1)(A).

[72] *Id.* at 22–23.

[73] *Id.* at 24.

490. By virtue of the acts described above, the Defendants knowingly or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, presented or caused to be presented, false claims to officers, employees, or agents of the United States Government, within the meaning of 31 U.S.C. § 3729(a)(1)(A).

491. The United States was unaware of the falsity of the records, statements, and claims made or caused to be made by Defendants. In reliance on the accuracy of the claims, information, records, and certifications submitted or caused to be submitted by Defendants, the United States paid claims that would not be paid if Defendants' illegal conduct was known.

492. As a result of Defendants' acts, the United States sustained damages and therefore is entitled to treble damages under the FCA to be determined at trial.

493. Additionally, the United States is entitled to civil penalties for each false claim made or caused to be made by Defendants arising from their illegal conduct as described above.

COUNT II
Violations of the FCA: Use of False Record or Statement Material to a False Claim
31 U.S.C. § 3729(a)(1)(B)

494. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

495. In pertinent part, the FCA establishes liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *See* 31 U.S.C. § 3729(a)(1)(B).

496. By virtue of the acts described above, Defendants knowingly or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, made, used, or caused to be made or used, a false record and statements.

497. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to get false claims paid or approved, within the meaning of 31 U.S.C. § 3729(a)(1)(B).

498. The records and statements were false in that they purported to show compliance with Federal laws and regulations, State laws and regulations, SAMHSA certifications and accreditations, the CIA, and Defendants' provider agreements.

499. The records and statements were material to a false or fraudulent claim.

500. Defendants knowingly made, used, or caused to be made or used these false records or statements with the intent to get or cause these false claims to be paid by the United States.

501. The United States was unaware of the falsity of the records, statements, certifications, and claims made or caused to be made by the Defendants

502. The United States paid claims that would not be paid if Defendants' illegal conduct was known.

503. By virtue of this conduct, the United States sustained damages and therefore is entitled to treble damages under the False Claims Act to be determined at trial.

504. Additionally, the United States is entitled to civil penalties for each false claim made or caused to be made by Defendants arising from their illegal conduct as described above.

COUNT III
Violations of the FCA: Conspiring to Submit False Claims
31 U.S.C. § 3729(a)(1)(C)

505. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

506. In pertinent part, the FCA establishes liability for "any person who . . . conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)." 31 U.S.C. § 3729(a)(1)(C).

507. By virtue of the acts described above, Defendants, acting in concert with each other and other contractors, agents, partners, and/or representatives, conspired to knowingly present or cause to be presented, false claims to the United States and knowingly made, used, or caused to be made or used, false records and statements, and omitting material facts, to get false claims paid or approved.

508. Defendants conspired to withhold information regarding their failure to comply with Federal laws and regulations, State laws and regulations, SAMHSA certifications and accreditations, the CIA, and Defendants' provider agreements.

509. As a result, the United States was unaware of the false claims submitted and caused to be submitted by the Defendants, and the United States paid claims that would not be paid if the Defendants' illegal conduct was known to the United States.

510. By virtue of this conduct, the United States sustained damages and therefore is entitled to treble damages under the False Claims Act to be determined at trial.

511. Additionally, the United States is entitled to civil penalties for each false claim made or caused to be made by Defendants arising from their illegal conduct as described above.

COUNT IV
Violations of the FCA: Submission of Express and Implied False Certifications
31 U.S.C. § 3729(a)(1)(B)

512. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

513. In pertinent part, the FCA establishes liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

514. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the United States in connection with Defendants' fraudulent and illegal practices.

515. Compliance with the CIA was an implied, and upon information and belief, also an express condition of payment of claims submitted to the United States in connection with Defendants' fraudulent and illegal practices. In fact, in its most recent 10-K, Defendant Acadia stated that noncompliance with the CIA "could lead to [its] suspension or exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs and repayment obligations."[74]

516. Defendants express and implied certifications of compliance with these laws, regulations, standards, and contracts was knowingly false.

517. The United States, unaware of the falsity of the records, statements, certifications and claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct, and the Defendants' illegal conduct was material to the Government's decision to pay claims.

518. By virtue of this conduct, the United States sustained damages and therefore is entitled to treble damages under the False Claims Act to be determined at trial.

519. Additionally, the United States is entitled to civil penalties for each false claim made or caused to be made by Defendants arising from their illegal conduct as described above.

[74] 10-K, supra note 2, at 30.

COUNT V
Violations of the FCA: Reverse False Claims
31 U.S.C. § 3729(a)(1)(G)

520. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

521. In pertinent part, the FCA also establishes liability for any person who "knowingly, makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government . . . ." 31 U.S.C. § 3729(a)(1)(G).

522. The FCA defines the term "obligation" to mean "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment . . . ." 31 U.S.C. § 3729(b)(3).

523. As described above, the CIA contained Stipulated Penalties for violations of its provisions.

524. As described above, Defendants violated the CIA by, *inter alia*, failing to implement or enforce compliance, training, and disclosure requirements and failing to disclose to HHS-OIG "Reportable Events."

525. By failing to comply with these provisions of the CIA, and concealing their violations of the CIA, Defendants knowingly made, used, or caused to be made or used, false records or statements material to an obligation to pay or transmit money or property to the Government.

526. Additionally, Defendants knowingly and improperly decreased and/or avoided their obligation to pay or transmit money, by way of Stipulated Penalties, to the United States.

527. By virtue of this conduct, the United States sustained damages and therefore is entitled to treble damages under the False Claims Act to be determined at trial.

528. Additionally, the United States is entitled to civil penalties for each false claim made or caused to be made by Defendants arising from their illegal conduct as described above.

COUNT VI
Violations of the North Carolina False Claims Act
N.C. Gen. Stat. § 1-605, *et seq.*

529. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

530. As described above, Defendants knowingly and/or with deliberate ignorance or reckless disregard of the truth or falsity of the information presented or caused to be presented false or fraudulent claims for payment or approval to the State of North Carolina.

531. As described above, Defendants made, used or caused to be made or used a false record or statement material to a false or fraudulent claim.

532. As described above, Defendants conspired to defraud the State of North Carolina by getting false or fraudulent claims paid or allowed.

533. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of North Carolina in connection with Defendants' fraudulent and illegal practices.

534. Moreover, compliance with the CIA was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of North Carolina in

connection with Defendants' fraudulent and illegal practices. In fact, in its most recent 10-K, Defendant Acadia stated that noncompliance with the CIA "could lead to [its] suspension or exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs and repayment obligations."[75]

535. The State of North Carolina, unaware of the falsity of the records, statements, certifications and claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct, and the Defendants' illegal conduct was material to the Government's decision to pay claims.

536. By reason of Defendants' acts, the State of North Carolina sustained damages and therefore is entitled to treble damages under the North Carolina False Claims Act to be determined at trial.

537. In addition, the State of North Carolina is entitled to recover civil monetary penalties, and other monetary relief as deemed appropriate.

PRAYER FOR RELIEF

WHEREFORE, Relator respectfully requests this Court to enter judgment against Defendants, as follows:

a. That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims and fraud alleged within this Complaint, as the FCA provides;

b. That the State of North Carolina be awarded damages in the amount of three times the damages sustained by the State of North Carolina because of the false claims and fraud alleged within this Complaint, as the North Carolina False Claims Act provides;

c. That civil penalties in the maximum amount allowable by law be imposed for each and every false claim that Defendants presented to the United States and/or its agencies;

[75] 10-K, supra note 2, at 30.

d. That civil penalties in the maximum amount allowable by law be imposed for each and every false claim that Defendants presented to the State of North Carolina and/or its agencies;

e. That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, expert fees, and expenses which Relator necessarily incurred in bringing and pressing this case;

f. That the Court grant permanent injunctive relief to prevent any recurrence of the FCA and the North Carolina False Claims Act for which redress is sought in this Complaint;

g. That Relator be awarded the maximum amount (i.e., relator's share) allowed to her pursuant to the FCA and the North Carolina False Claims Act; and

h. That this Court award such other and further relief as it deems proper.

DEMAND FOR JURY TRIAL

Relator, on behalf of herself, the United States, and the State of North Carolina, demands a jury trial on all claims triable alleged herein.

Respectfully submitted,

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